TABLE OF CONTENTS

TITLE I

GENERAL ISSUES

CHAPTER 1

Aim, scope and application

Article 1

Aim and scope

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

2. This Regulation lays down provisions on substances and preparations within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in preparations or in articles and to the placing on the market of preparations.

3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

Article 2

Application

1. This Regulation shall not apply to:

(a) radioactive substances within the scope of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation ([1]);

(b) substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;

(c) non-isolated intermediates;

(d) the carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.

2. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council ([2]) is not a substance, preparation or article within the meaning of Article 3 of this Regulation.

3. Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence.

4. This Regulation shall apply without prejudice to:

(a) Community workplace and environmental legislation, including Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([3]), Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control ([4]); Directive 98/24/EC, Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([5]) and Directive 2004/37/EC;

(b) Directive 76/768/EEC as regards testing involving vertebrate animals within the scope of that Directive.

5. The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used:

(a) in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ([6]) and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([7]);

(b) in food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:

(i) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ([8]);

([1]) OJ L 159, 29.6.1996, p. 1.
([2]) OJ L 114, 27.4.2006, p. 9.
([3]) OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003.
([4]) OJ L 257, 10.10.1996, p. 26. Directive as last amended by Regulation (EC) No 166/2006 of the European Parliament and of the Council (OJ L 33, 4.2.2006, p. 1).
([5]) OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).
([6]) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).
([7]) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006.
([8]) OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.

(ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([1]) and Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council ([2]);

(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([3]);

(iv) in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([4]).

6. The provisions of Title IV shall not apply to the following preparations in the finished state, intended for the final user:

(a) medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 and Directive 2001/82/EC and as defined in Directive 2001/83/EC;

(b) cosmetic products as defined in Directive 76/768/EEC;

(c) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC;

(d) food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:

(i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;

(ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;

(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;

(iv) in animal nutrition within the scope of Directive 82/471/EEC.

7. The following shall be exempted from Titles II, V and VI:

(a) substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;

(b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;

(c) substances on their own or in preparations, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain who shows that:

(i) the substance being re-imported is the same as the exported substance;

(ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;

(d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.

8. On-site isolated intermediates and transported isolated intermediates shall be exempted from:

(a) Chapter 1 of Title II, with the exception of Articles 8 and 9; and

(b) Title VII.

9. The provisions of Titles II and VI shall not apply to polymers.

CHAPTER 2

Definitions and general provision

Article 3

Definitions

For the purposes of this Regulation:

1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

([1]) OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003.
([2]) OJ L 84, 27.3.1999, p. 1. Decision as last amended by Decision 2006/253/EC (OJ L 91, 29.3.2006, p. 48).
([3]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
([4]) OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

2. preparation: means a mixture or solution composed of two or more substances;

3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

4. producer of an article: means any natural or legal person who makes or assembles an article within the Community;

5. polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

   (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

   (b) less than a simple weight majority of molecules of the same molecular weight.

   In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;

6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

7. registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

8. manufacturing: means production or extraction of substances in the natural state;

9. manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;

10. import: means the physical introduction into the customs territory of the Community;

11. importer: means any natural or legal person established within the Community who is responsible for import;

12. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

13. downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2 (7)(c) shall be regarded as a downstream user;

14. distributor: means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;

15. intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):

   (a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

   (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

   (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

16. site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

17. actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain;

18. Agency: means the European Chemicals Agency as established by this Regulation;

19. competent authority: means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

20. phase-in substance: means a substance which meets at least one of the following criteria:

   (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

   (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;

(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this;

21. notified substance: means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;

22. product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;

23. scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;

24. use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

25. registrant's own use: means an industrial or professional use by the registrant;

26. identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

27. full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;

29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;

30. per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;

31. restriction: means any condition for or prohibition of the manufacture, use or placing on the market;

32. supplier of a substance or a preparation: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;

33. supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;

34. recipient of a substance or a preparation: means a downstream user or a distributor being supplied with a substance or a preparation;

35. recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;

36. SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ([1]);

37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

39. substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

40. not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;

41. alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

([1]) OJ L 124, 20.5.2003, p. 36.

Article 4

General provision

Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

TITLE II

REGISTRATION OF SUBSTANCES

CHAPTER 1

General obligation to register and information requirements

Article 5

No data, no market

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

Article 6

General obligation to register substances on their own or in preparations

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of one tonne or more per year shall submit a registration to the Agency.

2. For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.

3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.

4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 7

Registration and notification of substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. The information to be notified shall include the following:

(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;

(b) the registration number(s) referred to in Article 20(1), if available;

(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;

(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;

(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);

(f) the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the Agency has grounds for suspecting that:

(i) the substance is released from the articles, and

(ii) the release of the substance from the articles presents a risk to human health or the environment;

(c) the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7. From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).

8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 8

Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

Article 9

Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1. Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:

(a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI;

(b) the identity of the substance, as specified in section 2 of Annex VI;

(c) the classification of the substance as specified in section 4 of Annex VI, if any;

(d) the estimated quantity as specified in section 3.1 of Annex VI;

(e) the list of customers referred to in paragraph 1, including their names and addresses.

The notification shall be accompanied by the fee required in accordance with Title IX.

The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3. The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the competent authority of the Member State(s) concerned.

4. The Agency may decide to impose conditions with the aim of ensuring that the substance or the preparation or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a preparation or article and that remaining quantities will be re-collected for disposal after the exemption period.

In such cases, the Agency may ask the notifier to provide additional necessary information.

5. In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.

6. The manufacturer or importer or producer of articles shall comply with any conditions imposed by the Agency in accordance with paragraph 4.

7. The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, or for substances that are not placed on the market, for a further maximum of ten years, upon request if the manufacturer or importer or producer of articles can demonstrate that such an extension is justified by the research and development programme.

8. The Agency shall forthwith communicate any draft decisions to the competent authorities of each Member State in which the manufacture, import, production or product and process orientated research takes place.

When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any comments made by such competent authorities.

9. The Agency and the competent authorities of the Member States concerned shall always keep confidential the information submitted in accordance with paragraphs 1 to 8.

10. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 4 and 7 of this Article.

Article 10

Information to be submitted for general registration purposes

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

(a) a technical dossier including:

(i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;

(ii) the identity of the substance as specified in section 2 of Annex VI;

(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;

(iv) the classification and labelling of the substance as specified in section 4 of Annex VI;

(v) guidance on safe use of the substance as specified in Section 5 of Annex VI;

(vi) study summaries of the information derived from the application of Annexes VII to XI;

(vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;

(viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;

(ix) proposals for testing where listed in Annexes IX and X;

(x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;

(xi) a request as to which of the information in Article 119 (2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

(b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

Article 11

Joint submission of data by multiple registrants

1. When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.

Subject to paragraph 3, the information specified in Article 10 (a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.

2. Each registrant need only comply with paragraph 1 for items of information specified in Article 10(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 12.

3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

(a) it would be disproportionately costly for him to submit this information jointly; or

(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

(c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 12

Information to be submitted depending on tonnage

1. The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:

(a) the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one tonne or more per year per manufacturer or importer;

(b) the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III;

(c) the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;

(d) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;

(e) the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.

2. As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.

3. This Article shall apply to producers of articles adapted as necessary.

Article 13

General requirements for generation of information on intrinsic properties of substances

1. Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.

2. These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Commission, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133(4), and the Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. Amendments to that Commission Regulation shall be adopted in accordance with the procedure specified in paragraph 3 and amendments to the Annexes of this Regulation shall be adopted in accordance with the procedure referred to in Article 131.

3. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. The Commission shall adopt that Regulation, designed to amend the non-essential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4).

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

4. Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.

5. If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex VI.

Article 14

Chemical safety report and duty to apply and recommend risk reduction measures

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a preparation or in an article or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of any of the following:

(a) the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;

(b) the concentration limits given in Annex I to Directive 67/548/EEC;

(c) the concentration limits given in Part B of Annex II to Directive 1999/45/EC;

(d) the concentration limits given in Part B of Annex III to Directive 1999/45/EC;

(e) the concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI of this Regulation;

(f) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII of this Regulation.

3. A chemical safety assessment of a substance shall include the following steps:

(a) human health hazard assessment;

(b) physicochemical hazard assessment;

(c) environmental hazard assessment;

(d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

(a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;

(b) risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.

5. The chemical safety report need not include consideration of the risks to human health from the following end uses:

(a) in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food [1];

(b) in cosmetic products within the scope of Directive 76/768/EEC.

[1] OJ L 338, 13.11.2004, p. 4.

6. Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.

7. Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

CHAPTER 2

Substances regarded as being registered

Article 15

Substances in plant protection and biocidal products

1. Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC [2] or in Commission Regulation (EEC) No 3600/92 [3], Commission Regulation (EC) No 703/2001 [4], Commission Regulation (EC) No 1490/2002 [5], or Commission Decision 2003/565/EC [6] and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1). Directive as last amended by Commission Directive 2006/136/EC (OJ L 349, 12.12.2006, p. 42).

[3] Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10). Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).

[4] Commission Regulation (EC) No 703/2001 of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs for those substances (OJ L 98, 7.4.2001, p. 6).

[5] Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 224, 21.8.2002, p. 23). Regulation as last amended by Regulation (EC) No 1744/2004 (OJ L 311, 8.10.2004, p. 23).

[6] Commission Decision 2003/565/EC of 25 July 2003 extending the time period provided for in Article 8(2) of Council Directive 91/414/EEC (OJ L 192, 31.7.2003, p. 40).

2. Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [1] or in Commission Regulation (EC) No 2032/2003 [2]on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

Article 16

Duties of the Commission, the Agency and registrants of substances regarded as being registered

1. The Commission or the relevant Community body shall make information equivalent to that required by Article 10 available to the Agency for substances regarded as registered according to Article 15. The Agency shall include this information or a reference thereto in its databases and notify the competent authorities thereof by 1 December 2008.

2. Articles 21, 22 and 25 to 28 shall not apply to uses of substances regarded as registered according to Article 15.

CHAPTER 3

Obligation to register and information requirements for certain types of isolated intermediates

Article 17

Registration of on-site isolated intermediates

1. Any manufacturer of an on-site isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

2. A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:

(a) the identity of the manufacturer as specified in Section 1 of Annex VI;

(b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;

(c) the classification of the intermediate as specified in Section 4 of Annex VI;

(d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

(e) a brief general description of the use, as specified in Section 3.5 of Annex VI;

(f) details of the risk management measures applied.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

If these conditions are not fulfilled, the registration shall include the information specified in Article 10.

Article 18

Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.

2. A registration for a transported isolated intermediate shall include all the following information:

(a) the identity of the manufacturer or importer as specified in Section 1 of Annex VI;

(b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;

(c) the classification of the intermediate as specified in Section 4 of Annex VI;

(d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

(e) a brief general description of the use, as specified in Section 3.5 of Annex VI;

[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/140/EC (OJ L 414, 30.12.2006, p. 78).

[2] OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63).

(f) information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3. A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII in addition to the information required under paragraph 2.

For the generation of this information, Article 13 shall apply.

4. Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

(b) procedural and control technologies shall be used that minimise emission and any resulting exposure;

(c) only properly trained and authorised personnel handle the substance;

(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;

(e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;

(f) substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 10.

Article 19

Joint submission of data on isolated intermediates by multiple registrants

1. When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, the following shall apply.

Subject to paragraph 2 of this Article, the information specified in Article 17(2)(c) and (d) and Article 18(2)(c) and (d) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as 'the lead registrant').

Each registrant shall subsequently submit separately the information specified in Article 17(2)(a), (b), (e) and (f) and Article 18 (2)(a),(b), (e) and (f).

2. A manufacturer or importer may submit the information referred to in Article 17(2)(c) or (d) and Article 18(2)(c) or (d) separately if:

(a) it would be disproportionately costly for him to submit this jointly; or

(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

(c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the manufacturer or importer shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

3. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

CHAPTER 4

Common provisions for all registrations

Article 20

Duties of the Agency

1. The Agency shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Agency.

2. The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 or under Articles 17 or 18, as well as the registration fee referred to in Article 6(4), Article 7(1) and (5), Article 17(2) or Article 18(2), have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

The Agency shall undertake the completeness check within three weeks of the submission date, or within three months of the relevant deadline of Article 23, as regards registrations of phase-in substances submitted in the course of the two-month period immediately preceding that deadline.

If a registration is incomplete, the Agency shall inform the registrant, before expiry of the three-week or three-month period referred to in the second subparagraph, as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.

The Agency shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

3. Once the registration is complete, the Agency shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. The Agency shall without delay communicate the registration number and registration date to the registrant concerned. The registration number shall be used for all subsequent correspondence regarding registration.

4. The Agency shall notify the competent authority of the relevant Member State within 30 days of the submission date, that the following information is available in the Agency database:

(a) the registration dossier together with the submission or registration number;

(b) the submission or registration date;

(c) the result of the completeness check; and

(d) any request for further information and deadline set in accordance with the third subparagraph of paragraph 2.

The relevant Member State shall be the Member State within which the manufacture takes place or the importer is established.

If the manufacturer has production sites in more than one Member State, the relevant Member State shall be the one in which the head office of the manufacturer is established. The other Member States where the production sites are established shall also be notified.

The Agency shall forthwith notify the competent authority of the relevant Member State(s) when any further information submitted by the registrant is available on the Agency database.

5. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 2 of this Article.

6. Where additional information for a particular substance is submitted to the Agency by a new registrant, the Agency shall notify the existing registrants that this information is available on the database for the purposes of Article 22.

Article 21

Manufacturing and import of substances

1. A registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the submission date, without prejudice to Article 27(8).

In the case of registrations of phase-in substances, such a registrant may continue the manufacture or import of the substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20 (2) within the three weeks after the submission date or, if submitted within the two-month period before the relevant deadline of Article 23, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three months from that deadline, without prejudice to Article 27 (8).

In the case of an update of a registration according to Article 22 a registrant may continue the manufacture or import of the substance, or the production or import of the article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the update date, without prejudice to Article 27(8).

2. If the Agency has informed the registrant that he is to submit further information in accordance with the third subparagraph of Article 20(2), the registrant may start the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from the Agency within the three weeks after receipt by the Agency of the further information necessary to complete his registration, without prejudice to Article 27(8).

3. If a lead registrant submits parts of the registration on behalf of one or more other registrants, as provided for in Articles 11 or 19, any of the other registrants may manufacture or import the substance or produce or import the articles only after the expiry of the time-limit laid down in paragraph 1 or 2 of this Article and provided that there is no indication to the contrary from the Agency in respect of the registration of the lead registrant acting on behalf of the others and his own registration.

Article 22

Further duties of registrants

1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:

(a) any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;

(b) any change in the composition of the substance as given in Section 2 of Annex VI;

(c) changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;

(d) new identified uses and new uses advised against as in Section 3.7 of Annex VI for which the substance is manufactured or imported;

(e) new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;

(f) any change in the classification and labelling of the substance;

(g) any update or amendment of the chemical safety report or Section 5 of Annex VI;

(h) the registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal shall be developed;

(i) any change in the access granted to information in the registration.

The Agency shall communicate this information to the competent authority of the relevant Member State.

2. A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 or take into account a decision made in accordance with Articles 60 and 73, within the deadline specified in that decision. The Agency shall notify the competent authority of the relevant Member State that the information is available on its database.

3. The Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration. In cases where the update is in accordance with Article 12(2) and with paragraph 1(c) of this Article then the Agency shall check the completeness of the information supplied by the registrant and Article 20(2) shall apply adapted as necessary.

4. In cases covered by Articles 11 or 19, each registrant shall submit separately the information specified in paragraph 1(c) of this Article.

5. An update shall be accompanied by the relevant part of the fee required in accordance with Title IX.

CHAPTER 5

Transitional provisions applicable to phase-in substances and notified substances

Article 23

Specific provisions for phase-in substances

1. Article 5, Article 6, Article 7(1), Article 17, Article 18 and Article 21 shall not apply until 1 December 2010 to the following substances:

(a) phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities reaching one tonne or more per year per manufacturer or per importer, at least once after 1 June 2007;

(b) phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007;

(c) phase-in substances manufactured in the Community or imported, in quantities reaching 1 000 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.

2. Article 5, Article 6, Article 7(1), Article 17, Article 18 and Article 21 shall not apply until 1 June 2013 to phase-in substances manufactured in the Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.

3. Article 5, Article 6, Article 7(1), Article 17, Article 18 and Article 21 shall not apply until 1 June 2018 to phase-in substances manufactured in the Community or imported, in quantities reaching one tonne or more per year per manufacturer or per importer, at least once after 1 June 2007.

4. Without prejudice to paragraphs 1 to 3, a registration can be submitted at any time before the relevant deadline.

5. This Article shall also apply to substances registered under Article 7 adapted as necessary.

Article 24

Notified substances

1. A notification in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of this Title and the Agency shall assign a registration number by 1 December 2008.

2. If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 12, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 10 and 12, unless it has already been submitted in accordance with those Articles.

TITLE III

DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

CHAPTER 1

Objectives and general rules

Article 25

Objectives and general rules

1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.

2. The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.

3. Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation at least 12 years previously can be used for the purposes of registration by another manufacturer or importer.

CHAPTER 2

Rules for non-phase-in substances and registrants of phase-in substances who have not pre-registered

Article 26

Duty to inquire prior to registration

1. Every potential registrant of a non-phase-in substance, or potential registrant of a phase-in substance who has not pre-registered in accordance with Article 28, shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:

(a) his identity as specified in Section 1 of Annex VI, with the exception of the use sites;

(b) the identity of the substance, as specified in Section 2 of Annex VI;

(c) which information requirements would require new studies involving vertebrate animals to be carried out by him;

(d) which information requirements would require other new studies to be carried out by him.

2. If the same substance has previously not been registered, the Agency shall inform the potential registrant accordingly.

3. If the same substance has previously been registered less than 12 years earlier, the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them.

Studies involving vertebrate animals shall not be repeated.

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 27.

4. If several potential registrants have made an inquiry in respect of the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants.

Article 27

Sharing of existing data in the case of registered substances

1. Where a substance has previously been registered less than 12 years earlier as referred to in Article 26(3), the potential registrant:

(a) shall, in the case of information involving tests on vertebrate animals; and

(b) may, in the case of information not involving tests on vertebrate animals,

request from the previous registrant(s) the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.

2. When a request for information has been made according to paragraph 1, the potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.

3. The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following cost sharing guidance based on those principles which is adopted by the Agency in accordance with Article 77(2)(g). Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

4. On agreement on the sharing of the information, the previous registrant shall make available to the new registrant the agreed information and shall give the new registrant the permission to refer to the previous registrant's full study report.

5. If there is failure to reach such an agreement, the potential registrant(s) shall inform the Agency and the previous registrant (s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the previous registrant(s).

6. Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier, subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 77(2)(g). Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

7. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 6 of this Article.

8. The registration waiting period in accordance with Article 21(1) for the new registrant shall be extended by a period of four months, if the previous registrant so requests.

CHAPTER 3

Rules for phase-in-substances

Article 28

Duty to pre-register for phase-in substances

1. In order to benefit from the transitional regime provided for in Article 23 each potential registrant of a phase-in substance in quantities of one tonne or more per year, including without limitation intermediates, shall submit all the following information to the Agency:

(a) the name of the substance as specified in Section 2 of Annex VI, including its EINECS and CAS number or, if not available, any other identity codes;

(b) his name and address and the name of the contact person and, where appropriate, the name and address of the person representing him in accordance with Article 4 as specified in Section 1 of Annex VI;

(c) the envisaged deadline for the registration and the tonnage band;

(d) the name(s) of substance(s) as specified in Section 2 of Annex VI, including their EINECS and CAS number or, if not available, any other identity codes, for which the available information is relevant for the application of Sections 1.3 and 1.5 of Annex XI.

2. The information referred to in paragraph 1 shall be submitted within a time period starting on 1 June 2008 and ending on 1 December 2008.

3. Registrants who do not submit the information required under paragraph 1 shall not be able to rely on Article 23.

4. The Agency shall by 1 January 2009 publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes, and the first envisaged registration deadline.

5. After the publication of the list a downstream user of a substance not appearing on the list may notify the Agency of his interest in the substance, his contact details and the details of his current supplier. The Agency shall publish on its website the name of the substance and on request provide contact details of the downstream user to a potential registrant.

6. Potential registrants who manufacture or import for the first time a phase-in substance in quantities of one tonne or more per year or use for the first time a phase-in substance in the context of production of articles or import for the first time an article containing a phase-in substance that would require registration, after 1 December 2008, shall be entitled to rely on Article 23 provided that they submit the information referred to in paragraph 1 of this Article to the Agency within six months of first manufacturing, importing or using the substance in quantities of one tonne or more per year and no later than 12 months before the relevant deadline in Article 23.

7. Manufacturers or importers of phase-in substances in quantities of less than one tonne per year that appear on the list published by the Agency in accordance with paragraph 4 of this Article, as well as downstream users of those substances and third parties holding information on those substances, may submit the information referred to in paragraph 1 of this Article or any other relevant information to the Agency for those substances, with the intention of being part of the substance information exchange forum as referred to in Article 29.

Article 29

Substance Information Exchange Forums

1. All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28, or whose information is held by the Agency in accordance with Article 15, for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline set out in Article 23 (3), shall be participants in a substance information exchange forum (SIEF).

2. The aim of each SIEF shall be to:

(a) facilitate, for the purposes of registration, the exchange of the information specified in Article 10(a) (vi) and (vii) between potential registrants, thereby avoiding the duplication of studies; and

(b) agree classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants.

3. SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purposes of paragraph 2(a) and arrange for such studies to be carried out. Each SIEF shall be operational until 1 June 2018.

Article 30

Sharing of data involving tests

1. Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study.

Within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 77(2)(g). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

2. If a relevant study involving tests is not available within the SIEF, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.

3. If the owner of a study as referred to in paragraph 1 which involves testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an) other participant(s), he shall not be able to proceed with registration until he provides the information to the other participants(s). The other participant(s) shall proceed with registration without fulfilling the relevant information requirement, explaining the reason for this in the registration dossier. The study shall not be repeated unless within 12 months of the date of registration of the other participant(s), the owner of this information has not provided it to them and the Agency decides that the test should be repeated by them. However, if a registration containing this information has already been submitted by another registrant, the Agency shall give the other participant(s) permission to refer to the information in his registration dossier (s). The other registrant shall have a claim on the other participant(s) for an equal share of the cost, provided he makes the full study report available to the other participant(s), which shall be enforceable in the national courts.

4. If the owner of a study as referred to in paragraph 1 which does not involve testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an)other participant(s), the other SIEF participants shall proceed with registration as if no relevant study was available in the SIEF.

5. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 2 or 3 of this Article.

6. The owner of the study who has refused to provide either proof of the cost or the study itself, as referred to in paragraph 3 or 4 of this Article, shall be penalised in accordance with Article 126.

TITLE IV

INFORMATION IN THE SUPPLY CHAIN

Article 31

Requirements for safety data sheets

1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:

(a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or

(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or

(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

2. Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a preparation and the actor in the supply chain has prepared a chemical safety assessment for that preparation, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:

(a) in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance posing human health or environmental hazards; or

(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous preparations at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or

(c) a substance for which there are Community workplace exposure limits.

4. The safety data sheet need not be supplied where dangerous substances or preparations offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

5. The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State(s) concerned provide otherwise.

6. The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/preparation and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI.

Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).

8. A safety data sheet shall be provided free of charge on paper or electronically.

9. Suppliers shall update the safety data sheet without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;

(b) once an authorisation has been granted or refused;

(c) once a restriction has been imposed.

The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

Article 32

Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required

1. Any supplier of a substance on its own or in a preparation who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:

(a) the registration number(s) referred to in Article 20(3), if available, for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;

(b) if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;

(c) details of any restriction imposed under Title VIII;

(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Section 3 of Annex XI.

2. The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a preparation after 1 June 2007.

3. Suppliers shall update this information without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;

(b) once an authorisation has been granted or refused;

(c) once a restriction has been imposed.

In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

Article 33

Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Article 34

Duty to communicate information on substances and preparations up the supply chain

Any actor in the supply chain of a substance or a preparation shall communicate the following information to the next actor or distributor up the supply chain:

(a) new information on hazardous properties, regardless of the uses concerned;

(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 35

Access to information for workers

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or preparations that they use or may be exposed to in the course of their work.

Article 36

Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or preparation. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the Agency, without prejudice to Titles II and VI.

2. In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or preparation concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

TITLE V

DOWNSTREAM USERS

Article 37

Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

1. A downstream user or distributor may provide information to assist in the preparation of a registration.

2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 14 either before he next supplies the substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.

For phase-in substances, the manufacturer, importer or downstream user shall comply with this request and with the obligations laid down in Article 14 before the relevant deadline in Article 23 has expired, provided that the downstream user makes his request at least 12 months before the deadline in question.

Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in Section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d).

4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.

A downstream user need not prepare such a chemical safety report in any of the following cases:

(a) a safety data sheet is not required to be communicated with the substance or preparation in accordance with Article 31;

(b) a chemical safety report is not required to be completed by his supplier in accordance with Article 14;

(c) the downstream user uses the substance or preparation in a total quantity of less than one tonne per year;

(d) the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;

(e) the substance is present in a preparation in a concentration lower than any of the concentrations set out in Article 14 (2);

(f) the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:

(a) the safety data sheet(s) supplied to him;

(b) his own chemical safety assessment;

(c) any information on risk management measures supplied to him in accordance with Article 32.

6. Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.

7. Downstream users shall keep their chemical safety report up to date and available.

8. A chemical safety report prepared in accordance with paragraph 4 of this Article need not include consideration of the risks to human health from the end uses set out in Article 14(5).

Article 38

Obligation for downstream users to report information

1. Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 6 or 18, the downstream user shall report to the Agency the information specified in paragraph 2 of this Article, in the following cases:

(a) the downstream user has to prepare a chemical safety report in accordance with Article 37(4); or

(b) the downstream user is relying on the exemptions in Article 37(4)(c) or (f).

2. The information reported by the downstream user shall include the following:

(a) his identity and contact details as specified in Section 1.1 of Annex VI;

(b) the registration number(s) referred to in Article 20(3), if available;

(c) the identity of the substance(s) as specified in Section 2.1 to 2.3.4 of Annex VI;

(d) the identity of the manufacturer(s) or the importer(s) or other supplier as specified in Section 1.1 of Annex VI;

(e) a brief general description of the use(s), as specified in Section 3.5 of Annex VI, and of the conditions of use(s);

(f) except where the downstream user is relying on the exemption in Article 37(4)(c), a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.

3. The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.

4. A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.

5. Except where a downstream user is relying on the exemption in Article 37(4)(c), reporting in accordance with paragraphs 1 to 4 of this Article shall not be required in respect of a substance, on its own or in a preparation, used by the downstream user in quantities of less than one tonne per year for that particular use.

Article 39

Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

2. Downstream users shall be required to comply with the requirements of Article 38 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

TITLE VI

EVALUATION

CHAPTER 1

Dossier evaluation

Article 40

Examination of testing proposals

1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.

2. Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with paragraph 3.

3. On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51:

(a) a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex I;

(b) a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;

(c) a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;

(d) a decision rejecting the testing proposal;

(e) a decision in accordance with points (a), (b) or (c), if several registrants or downstream users of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users, as appropriate, to perform the test on behalf of all of them.

4. The registrant or downstream user shall submit the information required to the Agency by the deadline set.

Article 41

Compliance check of registrations

1. The Agency may examine any registration in order to verify any of the following:

(a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;

(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;

(c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;

(d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.

2. The list of dossiers being checked for compliance by the Agency shall be made available to Member States competent authorities.

3. On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.

4. The registrant shall submit the information required to the Agency by the deadline set.

5. To ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking. The Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria:

(a) the dossier contains information in Article 10(a)(iv), (vi) and/or (vii) submitted separately as per Article 11(3); or

(b) the dossier is for a substance manufactured or imported in quantities of one tonne or more per year and does not meet the requirements of Annex VII applying under either Article 12(1)(a) or (b), as the case may be; or

(c) the dossier is for a substance listed in the Community rolling action plan referred to in Article 44(2).

6. Any third party may electronically submit information to the Agency relating to substances that appear on the list referred to in Article 28(4). The Agency shall consider this information together with the information submitted according to Article 124 when checking and selecting dossiers.

7. The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article 133(4).

Article 42

Check of information submitted and follow-up to dossier evaluation

1. The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.

2. Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4). The Agency shall use the information obtained from this evaluation for the purposes of Article 44.

Article 43

Procedure and time periods for examination of testing proposals

1. In the case of non phase-in substances, the Agency shall prepare a draft decision in accordance with Article 40(3) within 180 days of receiving a registration or downstream user report containing a testing proposal.

2. In the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 40(3):

(a) by 1 December 2012 for all registrations received by 1 December 2010 containing proposals for testing in order to fulfil the information requirements in Annexes IX and X;

(b) by 1 June 2016 for all registrations received by 1 June 2013 containing proposals for testing in order to fulfil the information requirements in Annex IX only;

(c) by 1 June 2022 for any registrations containing testing proposals received by 1 June 2018.

3. The list of registration dossiers being evaluated under Article 40 shall be made available to Member States.

CHAPTER 2

Substance evaluation

Article 44

Criteria for substance evaluation

1. In order to ensure a harmonised approach, the Agency shall in cooperation with the Member States develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider:

(a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;

(b) exposure information;

(c) tonnage, including aggregated tonnage from the registrations submitted by several registrants.

2. The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft Community rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. The Agency shall submit the first draft rolling action plan to the Member States by 1 December 2011. The Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year.

The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee set up under Article 76(1)(e) (hereinafter referred to as the Member State Committee) and shall publish the plan on its website, identifying the Member State who will carry out the evaluation of the substances listed therein as determined according to Article 45.

Article 45

Competent authority

1. The Agency shall be responsible for coordinating the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated. In doing so, the Agency shall rely on the competent authorities of Member States. In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf.

2. A Member State may choose (a) substance(s) from the draft Community rolling action plan, with the aim of becoming a competent authority for the purposes of Articles 46, 47 and 48. In the event of a substance from the draft Community rolling action plan not being chosen by any Member State, the Agency shall ensure that the substance is evaluated.

3. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority, the competent authority for the purposes of Articles 46, 47 and 48 shall be determined in accordance with the following procedure.

The Agency shall refer the matter to the Member State Committee, in order to agree which authority shall be the competent authority, taking into account the Member State in which the manufacturer(s) or importer(s) is located, the respective proportions of total Community gross domestic product, the number of substances already being evaluated by a Member State and the expertise available.

If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the Member States concerned shall adopt substances for evaluation accordingly.

If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 133(3), and the Member States concerned shall adopt substances for evaluation accordingly.

4. The competent authority identified in accordance with paragraphs 2 and 3 shall evaluate the allocated substances in accordance with this Chapter.

5. A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. The Agency shall decide whether to add this substance to the Community rolling action plan on the basis of an opinion from the Member State Committee. If the substance is added to the Community rolling action plan, the proposing Member State, or another Member State who agrees, shall evaluate that substance.

Article 46

Requests for further information and check of information submitted

1. If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the Community rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.

2. The registrant shall submit the information required to the Agency by the deadline set.

3. The competent authority shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

4. The competent authority shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2, and notify the Agency accordingly. If this deadline is exceeded, the evaluation shall be deemed to be finished.

Article 47

Coherence with other activities

1. An evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Title. Where information on intrinsic properties of a substance has been generated by reference to structurally related substance(s), the evaluation may also cover these related substances. In cases where a decision on an evaluation has been previously taken in accordance with Article 51 or Article 52, any draft decision requiring further information under Article 46 may be justified only by a change of circumstances or acquired knowledge.

2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 46 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 48

Follow-up to substance evaluation

Once the substance evaluation has been completed, the competent authority shall consider how to use the information obtained from this evaluation for the purposes of Article 59(3), Article 69(4) and Article 115(1). The competent authority shall inform the Agency of its conclusions as to whether or how to use the information obtained. The Agency shall in turn inform the Commission, the registrant and the competent authorities of the other Member States.

CHAPTER 3

Evaluation of intermediates

Article 49

Further information on on-site isolated intermediates

For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, where the competent authority of the Member State in whose territory the site is located considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:

(a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;

(b) examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

The procedure provided for in the first paragraph may be undertaken only by the competent authority referred to therein. The competent authority shall inform the Agency of the results of such an evaluation, which shall then inform the competent authorities of the other Member States and make the results available to them.

CHAPTER 4

Common provisions

Article 50

Registrants' and downstream users' rights

1. The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 46) and the Agency (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly.

2. If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform the Agency of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use. The Agency shall inform the competent authority of the Member State in which the registrant or downstream user is located.

3. The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the draft decision. In such cases, the registrant, or downstream user, shall inform the Agency of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report. The Agency shall inform the competent authority of the Member State in which the registrant or downstream user is located.

4. Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 46 in either or both of the following cases:

(a) where the competent authority prepares a dossier in accordance with Annex XV concluding that there is a potential long-term risk to human health or the environment justifying the need for further information;

(b) where the exposure to the substance manufactured or imported by the registrant(s), or to the substance in the article produced or imported by the registrant(s), or to the substance used by the downstream user(s) contributes significantly to that risk.

The procedure in Articles 69 to 73 shall apply *mutatis mutandis*.

Article 51

Adoption of decisions under dossier evaluation

1. The Agency shall notify its draft decision in accordance with Articles 40 or 41, together with the comments of the registrant, to the competent authorities of the Member States.

2. Within 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency.

3. If the Agency does not receive any proposals, it shall take the decision in the version notified under paragraph 1.

4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

5. The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account.

6. If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

7. If the Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 133(3).

8. An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 3 and 6 of this Article.

Article 52

Adoption of decisions under substance evaluation

1. The competent authority shall circulate its draft decision in accordance with Article 46, together with any comments by the registrant or downstream user, to the Agency and to the competent authorities of the other Member States.

2. The provisions of Article 51(2) to (8) shall apply *mutatis mutandis*.

Article 53

Cost sharing for tests without an agreement between registrants and/or downstream users

1. Where registrants or downstream users are required to perform a test as a result of a decision taken under this Title, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.

2. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

3. In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.

4. The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

Article 54

Publication of information on evaluation

By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

TITLE VII

AUTHORISATION

CHAPTER 1

Authorisation requirement

Article 55

Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Article 56

General provisions

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

(a) the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or

(b) the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or

(c) the date referred to in Article 58(1)(c)(i) has not been reached; or

(d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or

(e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.

3. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.

4. Paragraphs 1 and 2 shall not apply to the following uses of substances:

(a) uses in plant protection products within the scope of Directive 91/414/EEC;

(b) uses in biocidal products within the scope of Directive 98/8/EC;

(c) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels [1];

(d) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

5. In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

(a) uses in cosmetic products within the scope of Directive 76/768/EEC;

(b) uses in food contact materials within the scope of Regulation (EC) No 1935/2004.

6. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations:

(a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);

(b) for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous.

[1] OJ L 350, 28.12.1998, p. 58. Directive as amended by Regulation (EC) No 1882/2003.

Article 57

Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 58

Inclusion of substances in Annex XIV

1. Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall specify for each substance:

(a) the identity of the substance as specified in Section 2 of Annex VI;

(b) the intrinsic property (properties) of the substance referred to in Article 57;

(c) transitional arrangements:

(i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use;

(ii) a date or dates at least 18 months before the sunset date (s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;

(d) review periods for certain uses, if appropriate;

(e) uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

2. Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

3. Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

(a) PBT or vPvB properties; or

(b) wide dispersive use; or

(c) high volumes.

The number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV.

4. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 118 and 119 on access to information. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

The Agency shall update its recommendation, taking into account the comments received.

5. Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a preparation or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV.

6. A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in (an) article(s).

7. Substances for which all uses have been prohibited under Title VIII or by other Community legislation shall not be included in Annex XIV or shall be removed from it.

8. Substances which as a result of new information no longer meet the criteria of Article 57 shall be removed from Annex XIV in accordance with the procedure referred to in Article 133(4).

Article 59

Identification of substances referred to in Article 57

1. The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).

2. The Commission may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available to the Member States.

3. Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available within 30 days of receipt to the other Member States.

4. The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.

5. Within 60 days of circulation, the other Member States or the Agency may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to the Agency.

6. If the Agency does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3).

7. When comments are made or received, the Agency shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.

8. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency shall include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under Article 58(3).

9. If the Member State Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article 133(3).

10. The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.

CHAPTER 2

Granting of authorisations

Article 60

Granting of authorisations

1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

2. Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ([1]), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ([2]) or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ([3]).

3. Paragraph 2 shall not apply to:

(a) substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;

(b) substances meeting the criteria in Article 57(d) or (e);

(c) substances identified under Article 57(f) having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties.

4. If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account the opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis referred to in Article 64(4)(a) and (b):

(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);

(d) available information on the risks to human health or the environment of any alternative substances or technologies.

5. When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:

(a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;

(b) the technical and economic feasibility of alternatives for the applicant.

6. A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII.

7. An authorisation shall be granted only if the application is made in conformity with the requirements of Article 62.

8. Authorisations shall be subject to a time-limited review without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring. The duration of the time-limited review for any authorisation shall be determined on a case-by-case basis taking into account all relevant information including the elements listed in paragraph 4(a) to (d), as appropriate.

9. The authorisation shall specify:

(a) the person(s) to whom the authorisation is granted;

(b) the identity of the substance(s);

(c) the use(s) for which the authorisation is granted;

(d) any conditions under which the authorisation is granted;

(e) the time-limited review period;

(f) any monitoring arrangement.

10. Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible.

Article 61

Review of authorisations

1. Authorisations granted in accordance with Article 60 shall be regarded as valid until the Commission decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.

([1]) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003.
([2]) OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.
([3]) OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

A holder of an authorisation granted in accordance with Article 60 shall submit an update of the analysis of alternatives referred to in Article 62(4)(e), including information about any relevant research and development activities by the applicant, if appropriate, and any substitution plan submitted under Article 62(4)(f). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 60(5), he shall submit a substitution plan, including a timetable for proposed actions by the applicant. If the holder cannot demonstrate that the risk is adequately controlled, he shall also submit an update of the socio-economic analysis contained in the original application.

If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.

If any other elements of the original application have changed, he shall also submit updates of these element(s).

When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorisation in the context of the review shall be taken in accordance with the procedure referred to in Article 64 applied *mutatis mutandis*.

2. Authorisations may be reviewed at any time if:

(a) the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or

(b) new information on possible substitutes becomes available.

The Commission shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 64.

3. In its review decision the Commission may, if circumstances have changed and taking into account the principle of proportionality, amend or withdraw the authorisation, if under the changed circumstances it would not have been granted or if suitable alternatives in accordance with Article 60(5) become available. In the latter case the Commission shall require the holder of the authorisation to present a substitution plan if he has not already done so as part of his application or update.

In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account the principle of proportionality.

4. If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned may be reviewed.

5. If the environmental objectives as referred to in Article 4 (1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

6. If a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants [1], the Commission shall withdraw the authorisation for that use.

Article 62

Applications for authorisations

1. An application for an authorisation shall be made to the Agency.

2. Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.

3. Applications may be made for one or several substances, that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.

4. An application for authorisation shall include the following information:

(a) the identity of the substance(s), as referred to in Section 2 of Annex VI;

(b) the name and contact details of the person or persons making the application;

(c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;

(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;

(e) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;

[1] OJ L 158, 30.4.2004, p. 7, corrected in OJ L 229, 29.6.2004, p. 5. Regulation as amended by Council Regulation (EC) No 1195/2006 (OJ L 217, 8.8.2006, p. 1).

(f) where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.

5. The application may include:

(a) a socio-economic analysis conducted in accordance with Annex XVI;

(b) a justification for not considering risks to human health and the environment arising either from:

(i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or

(ii) discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.

6. The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC.

7. An application for an authorisation shall be accompanied by the fee required in accordance with Title IX.

Article 63

Subsequent applications for authorisation

1. If an application has been made for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application.

2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application submitted in accordance with Article 62(4)(d), (e) and (f) and (5)(a), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.

3. Before referring to any previous application in accordance with paragraphs 1 and 2, the subsequent applicant shall update the information of the original application as necessary.

Article 64

Procedure for authorisation decisions

1. The Agency shall acknowledge the date of receipt of the application. The Agency's Committees for Risk Assessment and Socio-economic Analysis shall give their draft opinions within ten months of the date of receipt of the application.

2. The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

3. In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Committees shall, in consultation with each other, make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62. The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.

4. The draft opinions shall include the following elements:

(a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;

(b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

5. The Agency shall send these draft opinions to the applicant by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.

If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the Member States and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. The Committees shall consider the comments and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the opinions, with the written argumentation attached, to the Commission, the Member States and the applicant.

6. The Agency shall determine in accordance with Articles 118 and 119 which parts of its opinions and parts of any attachments thereto should be made publicly available on its website.

7. In cases covered by Article 63(1), the Agency shall treat the applications together, provided the deadlines for the first application can be met.

8. The Commission shall prepare a draft authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article 133(3).

9. Summaries of the Commission decisions, including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, shall be published in the Official Journal of the European Union and shall be made publicly available in a database established and kept up to date by the Agency.

10. In cases covered by Article 63(2), the deadline set out in paragraph 1 of this Article shall be shortened to five months.

CHAPTER 3

Authorisations in the supply chain

Article 65

Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users referred to in Article 56(2) including the substances in a preparation, shall include the authorisation number on the label before they place the substance or a preparation containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9).

Article 66

Downstream users

1. Downstream users using a substance in accordance with Article 56(2) shall notify the Agency within three months of the first supply of the substance.

2. The Agency shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. The Agency shall grant access to this register to the competent authorities of the Member States.

TITLE VIII

RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

CHAPTER 1

General issues

Article 67

General provisions

1. A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

2. Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by Directive 76/768/EEC, with regard to restrictions addressing the risks to human health within the scope of that Directive.

3. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by 1 June 2009.

CHAPTER 2

Restrictions process

Article 68

Introducing new and amending current restrictions

1. When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.

2. For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.

Article 69

Preparation of a proposal

1. If the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XV.

2. After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.

3. Within 12 months of the receipt of the request from the Commission in paragraph 1 and if this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

4. If a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed it shall notify the Agency that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. If the substance is not on the list maintained by the Agency referred to in paragraph 5 of this Article, the Member State shall prepare a dossier which conforms to the requirements of Annex XV within 12 months of the notification to the Agency. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XV, in order to initiate the restrictions process.

The Agency or Member States shall refer to any dossier, chemical safety report or risk assessment submitted to the Agency or Member State under this Regulation. The Agency or Member States shall also refer to any relevant risk assessment submitted for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency or Member State concerned on request.

The Committee for Risk Assessment and the Committee for Socio-economic Analysis shall check whether the dossier submitted conforms to the requirements of Annex XV. Within 30 days of receipt, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Chapter shall be terminated. The Agency shall publish without delay the intention of the Commission or of a Member State to instigate a restriction procedure for a substance and shall inform those who submitted a registration for that substance.

5. The Agency shall maintain a list of substances for which a dossier conforming to the requirements of Annex XV is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction. If a substance is on the list, no other such dossier shall be prepared. If it is proposed by either a Member State or the Agency that an existing restriction listed in Annex XVII should be re-examined a decision on whether to do so shall be taken in accordance with the procedure referred to in Article 133(2) based on evidence presented by the Member State or the Agency.

6. Without prejudice to Articles 118 and 119, the Agency shall make publicly available on its website all dossiers conforming with Annex XV including the restrictions suggested pursuant to paragraphs 3 and 4 of this Article without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly within six months of the date of publication:

(a) comments on dossiers and the suggested restrictions;

(b) a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions. It shall conform to the requirements in Annex XVI.

Article 70

Agency opinion: Committee for Risk Assessment

Within nine months of the date of publication referred to in Article 69(6), the Committee for Risk Assessment shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the Member State dossier or of the dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in Article 69(6)(a).

Article 71

Agency opinion: Committee for Socio-economic Analysis

1. Within 12 months of the date of publication referred to in Article 69(6), the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.

2. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under Article 69(6)(b) and under paragraph 1 of this Article.

3. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions suggested, the Agency may postpone the deadline for the opinion of the Committee for Socio-economic Analysis by a maximum of 90 days.

Article 72

Submission of an opinion to the Commission

1. The Agency shall submit to the Commission without delay the opinions of the Committees for Risk Assessment and Socio-economic Analysis on restrictions suggested for substances on their own, in preparations or in articles. If one or both of the Committees do not formulate an opinion by the deadline set in Article 70 and Article 71(1) the Agency shall inform the Commission accordingly, stating the reasons.

2. Without prejudice to Articles 118 and 119 the Agency shall publish the opinions of the two Committees on its website without delay.

3. The Agency shall provide the Commission and/or Member State on request with all documents and evidence submitted to or considered by it.

Article 73

Commission decision

1. If the conditions laid down in Article 68 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the opinion of the Committee for Socio-economic Analysis or by the end of the deadline established under Article 71 if that Committee does not form an opinion, whichever is the earlier.

Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences.

2. A final decision shall be taken in accordance with the procedure referred to in Article 133(4). The Commission shall send the draft amendment to the Member States at least 45 days before voting.

TITLE IX

FEES AND CHARGES

Article 74

Fees and charges

1. The fees that are required according to Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2), Article 18(2), Article 19(3), Article 22(5), Article 62(7) and Article 92(3) shall be specified in a Commission Regulation adopted in accordance with the procedure referred to in Article 133(3) by 1 June 2008.

2. A fee need not be paid for a registration of a substance in a quantity of between 1 and 10 tonnes where the registration dossier contains the full information in Annex VII.

3. The structure and amount of the fees referred to in paragraph 1 shall take account of the work required by this Regulation to be carried out by the Agency and the competent authority and shall be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of the Agency's revenue pursuant to Article 96(1) is sufficient to cover the cost of the services delivered. The fees set for registration shall take into account the work that may be done pursuant to Title VI.

In the case of Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2) and Article 18(2), the structure and amount of fees shall take account of the tonnage range of the substance being registered.

In all cases, a reduced fee shall be set for SMEs.

In the case of Article 11(4), the structure and amount of fees shall take into account whether information has been submitted jointly or separately.

In the case of a request made under Article 10(a)(xi), the structure and amount of fees shall take into account the work required by the Agency in assessing the justification.

4. The Regulation referred to in paragraph 1 shall specify the circumstances under which a proportion of the fees will be transferred to the relevant Member State competent authority.

5. The Agency may collect charges for other services it provides.

TITLE X

AGENCY

Article 75

Establishment and review

1. A European Chemicals Agency is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects.

2. The Agency shall be subject to a review by 1 June 2012.

Article 76

Composition

1. The Agency shall comprise:

(a) a Management Board, which shall exercise the responsibilities set out in Article 78;

(b) an Executive Director, who shall exercise the responsibilities set out in Article 83;

(c) a Committee for Risk Assessment, which shall be responsible for preparing the opinion of the Agency on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling under Title XI and any other questions that arise from the operation of this Regulation relating to risks to human health or the environment;

(d) a Committee for Socio-economic Analysis, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of this Regulation relating to the socio-economic impact of possible legislative action on substances;

(e) a Member State Committee, which shall be responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States under Title VI and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;

(f) a Forum for Exchange of Information on Enforcement (hereinafter referred to as the Forum) which shall coordinate a network of Member States authorities responsible for enforcement of this Regulation;

(g) a Secretariat, which shall work under the leadership of the Executive Director and provide technical, scientific and administrative support for the Committees and the Forum and ensure appropriate coordination between them. It shall also undertake the work required of the Agency under the procedures for pre-registration, registration and evaluation as well as preparation of guidance, database maintenance and information provision;

(h) a Board of Appeal, which shall decide on appeals against decisions taken by the Agency.

2. The Committees referred to in points (c), (d) and (e) of paragraph 1 (hereinafter referred to as the Committees) and the Forum may each establish working groups. For this purpose they shall adopt, in accordance with their rules of procedure, precise arrangements for delegating certain tasks to these working groups.

3. The Committees and the Forum may, if they consider it appropriate, seek advice on important questions of a general scientific or ethical nature from appropriate sources of expertise.

Article 77

Tasks

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2. The Secretariat shall undertake the following tasks:

(a) performing the tasks allotted to it under Title II; including facilitating the efficient registration of imported substances, in a way consistent with the Community's international trading obligations towards third countries;

(b) performing the tasks allotted to it under Title III;

(c) performing the tasks allotted to it under Title VI;

(d) performing the tasks allotted to it under Title VIII;

(e) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list. It shall make the information identified in Article 119 (1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 118;

(f) making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 119(1);

(g) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;

(h) providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States under Title XIII;

(i) providing guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances, on their own, in preparations or in articles;

(j) providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1);

(k) preparing explanatory information on this Regulation for other stakeholders;

(l) at the Commission's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;

(m) keeping a Manual of Decisions and Opinions based on conclusions from the Member State Committee regarding interpretation and implementation of this Regulation;

(n) notification of decisions taken by the Agency;

(o) provision of formats for submission of information to the Agency.

3. The Committees shall undertake the following tasks:

(a) performing the tasks allotted to them under Titles VI to XI;

(b) at the Executive Director's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;

(c) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles.

4. The Forum shall undertake the following tasks:

(a) spreading good practice and highlighting problems at Community level;

(b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;

(c) coordinating exchange of inspectors;

(d) identifying enforcement strategies, as well as best practice in enforcement;

(e) developing working methods and tools of use to local inspectors;

(f) developing an electronic information exchange procedure;

(g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;

(h) examining proposals for restrictions with a view to advising on enforceability.

Article 78

Powers of the Management Board

The Management Board shall appoint the Executive Director pursuant to Article 84 and an accounting officer in accordance with Article 43 of Regulation (EC, Euratom) No 2343/2002.

It shall adopt:

(a) by 30 April each year, the general report of the Agency for the previous year;

(b) by 31 October each year the work programme of the Agency for the coming year;

(c) the final budget of the Agency pursuant to Article 96 before the beginning of the financial year, adjusting it, where necessary, according to the Community contribution and any other revenue of the Agency;

(d) a multiannual work programme, which shall be regularly revised.

It shall adopt the internal rules and procedures of the Agency. These rules shall be made public.

It shall perform its duties in relation to the Agency's budget pursuant to Articles 96, 97 and 103.

It shall exercise disciplinary authority over the Executive Director.

It shall adopt its rules of procedure.

It shall appoint the Chairman, the members and alternates of the Board of Appeal in accordance with Article 89.

It shall appoint the members of the Agency committees as set out in Article 85.

It shall forward annually any information relevant to the outcome of the evaluation procedures in accordance with Article 96(6).

Article 79

Composition of the Management Board

1. The Management Board shall be composed of one representative from each Member State and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights and in addition two independent persons appointed by the European Parliament.

Each Member State shall nominate a member to the Management Board. The members thus nominated shall be appointed by the Council.

2. Members shall be appointed on the basis of their relevant experience and expertise in the field of chemical safety or the regulation of chemicals whilst ensuring there is relevant expertise amongst the board members in the fields of general, financial and legal matters.

3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission shall identify half of its appointees, and the Council shall identify 12 of its appointees, for whom this period shall be six years.

Article 80

Chairmanship of the Management Board

1. The Management Board shall elect a Chairman and a Deputy-Chairman from among the members with voting rights. The Deputy-Chairman shall automatically take the place of the Chairman if he is prevented from attending to his duties.

2. The terms of office of the Chairman and the Deputy-Chairman shall be two years and shall expire when they cease to be members of the Management Board. The term of office shall be renewable once.

Article 81

Meetings of the Management Board

1. The meetings of the Management Board shall be convened by invitation of its Chairman or at the request of at least one third of the Board members.

2. The Executive Director shall take part in the meetings of the Management Board, without voting rights.

3. The Chairmen of the Committees and the Chairman of the Forum, as referred to in Article 76(1)(c) to (f), are entitled to attend the meetings of the Management Board without voting rights.

Article 82

Voting of the Management Board

The Management Board shall adopt rules of procedure for voting, including the conditions for a member to vote on behalf of another member. The Management Board shall act by a two-thirds majority of all members with the right to vote.

Article 83

Duties and powers of the Executive Director

1. The Agency shall be managed by its Executive Director, who shall perform his duties in the interests of the Community, and independently of any specific interests.

2. The Executive Director shall be the legal representative of the Agency. He shall be responsible for:

(a) the day-to-day administration of the Agency;

(b) managing all the Agency resources necessary for carrying out its tasks;

(c) ensuring that the time-limits laid down in Community legislation for the adoption of opinions by the Agency are complied with;

(d) ensuring appropriate and timely coordination between the Committees and the Forum;

(e) concluding and managing necessary contracts with service providers;

(f) the preparation of the statement of revenue and expenditure and the implementation of the budget of the Agency pursuant to Articles 96 and 97;

(g) all staff matters;

(h) providing the secretariat for the Management Board;

(i) preparing draft opinions of the Management Board concerning the proposed rules of procedure of the Committees and of the Forum;

(j) making arrangements, upon request from the Management Board, for the execution of any further function(s) (within the remit of Article 77) allotted to the Agency by delegation from the Commission;

(k) establishing and maintaining a regular dialogue with the European Parliament;

(l) determining the terms and conditions for use of software packages;

(m) rectifying a decision made by the Agency following an appeal and after consulting the Chairman of the Board of Appeal.

3. Each year, the Executive Director shall submit the following to the Management Board for approval:

(a) a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction received by the Agency and opined upon, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; complaints received and the action taken; an overview of the activities of the Forum;

(b) a draft work-programme for the coming year;

(c) the draft annual accounts;

(d) the draft forecast budget for the coming year;

(e) a draft multiannual work programme.

The Executive Director shall, following approval by the Management Board, forward the work programme for the coming year and the multiannual work programme to the Member States, the European Parliament, the Council and the Commission, and shall have them published.

The Executive Director shall, following approval by the Management Board, forward the Agency's general report to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and shall have it published.

Article 84

Appointment of the Executive Director

1. The Executive Director of the Agency shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and in other periodicals or on Internet sites.

The Executive Director shall be appointed on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The Management Board shall take its decision by a two-thirds majority of all members with a right to vote.

Power to dismiss the Executive Director shall lie with the Management Board, in accordance with the same procedure.

Before being appointed, the candidate selected by the Management Board shall be invited as soon as possible to make a statement before the European Parliament and to answer questions from Members of Parliament.

2. The term of the office of the Executive Director shall be five years. It may be prolonged by the Management Board once for another period of up to five years.

Article 85

Establishment of the Committees

1. Each Member State may nominate candidates to membership of the Committee for Risk Assessment. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 77(3).

2. Each Member State may nominate candidates to membership of the Committee for Socio-economic Analysis. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 77(3).

3. Each Member State shall appoint one member to the Member State Committee.

4. The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.

Members of the Committees shall be appointed for a term of three years which shall be renewable.

The members of the Management Board may not be members of the Committees.

The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.

The Executive Director or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and working groups convened by the Agency or its committees as observers. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of the Committee members, or the Management Board.

5. The members of each Committee appointed following nomination by a Member State shall ensure that there is appropriate coordination between the tasks of the Agency and the work of their Member State competent authority.

6. The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.

7. The Member States shall refrain from giving the members of the Committee for Risk Assessment or of the Committee for Socio-Economic Analysis, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.

8. When preparing an opinion, each Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members, including their grounds. The minority position(s), including their grounds, shall also be published.

9. Each Committee shall draft a proposal for its own rules of procedure, to be approved by the Management Board, within six months of the Committees first being appointed.

These rules shall in particular lay down the procedures for replacing members, the procedures for delegating certain tasks to working groups, the creation of working groups and the establishment of a procedure for the urgent adoption of opinions. The Chairman of each Committee shall be an employee of the Agency.

Article 86

Establishment of the Forum

1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.

The Forum shall aim to have a broad range of relevant expertise among its members. To this end the Forum may co-opt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable. Members of the Management Board may not be members of the Forum.

The members of the Forum may be accompanied by scientific and technical advisers.

The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of Forum members, or the Management Board.

2. The members of the Forum appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State competent authority.

3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.

4. The Forum shall draft a proposal for its own rules of procedure, to be adopted by the Management Board, within six months of the Forum first being appointed.

These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members and the procedures for delegating certain tasks to working groups.

Article 87

Rapporteurs of Committees and use of experts

1. Where, in accordance with Article 77, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

2. Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 77, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.

3. The provision of services by Committee members or any expert serving on a working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

4. The provision of services for which there are several potential providers may require a call for an expression of interest:

(a) if the scientific and technical context allows; and

(b) if it is compatible with the duties of the Agency, in particular the need to provide a high level of protection of human health and the environment.

The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

5. The Agency may use the services of experts for the discharge of other specific tasks for which it is responsible.

Article 88

Qualification and interests

1. The membership of the Committees and of the Forum shall be made public. Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests. When each appointment is published, the professional qualifications of each member shall be specified.

2. Members of the Management Board, the Executive Director and members of the Committees and of the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing and, without prejudice to paragraph 1, be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.

3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees and of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall not participate in any voting on the relevant agenda point.

Article 89

Establishment of the Board of Appeal

1. The Board of Appeal shall consist of a Chairman and two other members.

2. The Chairman and the two members shall have alternates who shall represent them in their absence.

3. The Chairman, the other members and the alternates shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and in other periodicals or on Internet sites. They shall be appointed on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates adopted by the Commission.

The Management Board may appoint additional members and their alternates, on recommendation by the Executive Director, following the same procedure, if this is necessary to ensure that the appeals can be processed at a satisfactory rate.

4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article 133(3).

5. The Chairman and the members shall have equal voting rights.

Article 90

Members of the Board of Appeal

1. The term of office of the members of the Board of Appeal, including the Chairman and the alternates shall be five years. It may be prolonged once.

2. The members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.

3. The members of the Board of Appeal may not perform any other duties in the Agency.

4. The members of the Board of Appeal may not be removed either from office or from the list during their respective terms, unless there are serious grounds for such removal and the Commission, after obtaining the opinion of the Management Board, takes a decision to this effect.

5. Members of the Board of Appeal may not take part in any appeal proceedings if they have any personal interest therein, or if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal.

6. If a member of the Board of Appeal considers for reasons mentioned in paragraph 5 that he must not take part in a specific appeal proceedings, he shall inform the Board of Appeal accordingly. Members of the Board may be objected to by any party to the appeal proceedings on any of the grounds mentioned in paragraph 5, or if suspected of partiality. No objection may be based on the nationality of members.

7. The Board of Appeal shall decide as to the action to be taken in the cases specified in paragraphs 5 and 6 without the participation of the member concerned. For the purposes of taking this decision, the member concerned shall be replaced on the Board of Appeal by an alternate.

Article 91

Decisions subject to appeal

1. An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51.

2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

Article 92

Persons entitled to appeal, time-limits, fees and form

1. Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former.

2. The appeal, together with the statements of the grounds thereof, shall be filed in writing to the Agency within three months of the notification of the decision to the person concerned, or in the absence thereof, of the day on which it became known to the latter, unless otherwise provided in this Regulation.

3. A fee may be payable by persons bringing an appeal against an Agency decision, in accordance with Title IX.

Article 93

Examination and decisions on appeal

1. If, after consultation with the Chairman of the Board of Appeal, the Executive Director considers the appeal to be admissible and well founded he may rectify the decision within 30 days of the appeal being filed in accordance with Article 92 (2).

2. In cases other than those referred to in paragraph 1 of this Article, the Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed in accordance with Article 92(2). In the affirmative, the appeal shall be remitted to the Board of Appeal for examination of the grounds. Parties to the appeal proceedings shall be entitled to make an oral presentation during the procedure.

3. The Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

4. The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article 133(3).

Article 94

Actions before the Court of First Instance and the Court of Justice

1. An action may be brought before the Court of First Instance or the Court of Justice, in accordance with Article 230 of the Treaty, contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the Agency.

2. Should the Agency fail to take a decision, proceedings for failure to act may be brought before the Court of First Instance or the Court of Justice in accordance with Article 232 of the Treaty.

3. The Agency shall be required to take the necessary measures to comply with the judgment of the Court of First Instance or the Court of Justice.

Article 95

Conflicts of opinion with other bodies

1. The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of other bodies established under Community law, including Community Agencies, carrying out a similar task in relation to issues of common concern.

2. Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.

3. Where there is a fundamental conflict over scientific or technical points and the body concerned is a Community Agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

Article 96

The budget of the Agency

1. The revenues of the Agency shall consist of:

(a) a subsidy from the Community, entered in the general budget of the European Communities (Commission Section);

(b) the fees paid by undertakings;

(c) any voluntary contribution from the Member States.

2. The expenditure of the Agency shall include the staff, administrative, infrastructure and operational expenses.

3. By 15 February of each year at the latest, the Executive Director shall draw up a preliminary draft budget covering the operational expenditure and the programme of work anticipated for the following financial year, and shall forward this preliminary draft to the Management Board together with an establishment plan accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.

6. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the budgetary authority) together with the preliminary draft budget of the European Communities.

7. On the basis of the estimate, the Commission shall enter in the preliminary draft budget of the European Communities the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

8. The budgetary authority shall authorise the appropriations for the subsidy to the Agency.

The budgetary authority shall adopt the establishment plan for the Agency.

9. The budget of the Agency shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Communities. Where appropriate, it shall be adjusted accordingly.

10. Any modification to the budget, including the establishment plan, shall follow the procedure referred to above.

11. The Management Board shall, without delay, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

Article 97

Implementation of the budget of the Agency

1. The Executive Director shall perform the duties of authorising officer and shall implement the Agency's budget.

2. Monitoring of the commitment and payment of all the Agency's expenditure and of the establishment and recovery of all the Agency's revenue shall be carried out by the Accounting Officer of the Agency.

3. By 1 March at the latest following each financial year, the Agency's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1].

[1] OJ L 248, 16.9.2002, p. 1. Regulation as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p. 1).

4. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Agency's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for that financial year shall also be forwarded to the European Parliament and the Council.

5. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 129 of Regulation (EC, Euratom) No 1605/2002, the Executive Director shall draw up the Agency's final accounts under his own responsibility and forward them to the Management Board for an opinion.

6. The Management Board shall deliver an opinion on the Agency's final accounts.

7. By 1 July of the following year at the latest, the Executive Director shall send the final accounts, together with the opinion of the Management Board, to the European Parliament, the Council, the Commission and the Court of Auditors.

8. The final accounts shall be published.

9. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.

10. The European Parliament, upon a recommendation from the Council, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 98

Combating fraud

1. In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) [1] shall apply without restrictions to the Agency.

2. The Agency shall be bound by the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office (OLAF) [2] and shall issue, without delay, the appropriate provisions applicable to all of its staff.

3. The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Agency's funding and the agents responsible for allocating it.

Article 99

Financial rules

The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Regulation (EC, Euratom) No 2343/2002 unless specifically necessary for the Agency's operation and with the Commission's prior consent.

Article 100

Legal personality of the Agency

1. The Agency shall be a body of the Community and shall have legal personality. In each Member State it shall enjoy the most extensive legal capacity accorded to legal persons under their laws. In particular it may acquire and dispose of movable and immovable property and may be a party to legal proceedings.

2. The Agency shall be represented by its Executive Director.

Article 101

Liability of the Agency

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. The Court of Justice shall have jurisdiction pursuant to any arbitration clause contained in a contract concluded by the Agency.

2. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or by its servants in the performance of their duties.

The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damages.

3. The personal financial and disciplinary liability of its servants towards the Agency shall be governed by the relevant rules applying to the staff of the Agency.

[1] OJ L 136, 31.5.1999, p. 1.
[2] OJ L 136, 31.5.1999, p. 15.

Article 102

Privileges and immunities of the Agency

The Protocol on the Privileges and Immunities of the European Communities shall apply to the Agency.

Article 103

Staff rules and regulations

1. The staff of the Agency shall be subject to the Regulations and Rules applicable to officials and other servants of the European Communities. In respect of its staff, the Agency shall exercise the powers which have been devolved to the appointing authority.

2. The Management Board shall, in agreement with the Commission, adopt the necessary implementing provisions.

3. The Agency's staff shall consist of officials assigned or seconded by the Commission or Member States on a temporary basis and of other servants recruited by the Agency as necessary to carry out its tasks. The Agency shall recruit its personnel on the basis of a staffing plan to be included in the multiannual work programme referred to in Article 78(d).

Article 104

Languages

1. Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community [1] shall apply to the Agency.

2. The translation services required for the functioning of the Agency shall be provided by the Translation Centre of the bodies of the European Union.

Article 105

Duty of confidentiality

Members of the Management Board, members of the Committees and of the Forum, experts and officials and other servants of the Agency, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the duty of professional secrecy.

Article 106

Participation of third countries

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of third countries to participate in the work of the Agency.

[1] OJ 17, 6.10.1958, p. 385/58. Regulation as last amended by Council Regulation (EC) No 920/2005 (OJ L 156, 18.6.2005, p. 3).

Article 107

Participation of international organisations

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of international organisations with interests in the field of chemicals regulation to participate as observers in the work of the Agency.

Article 108

Contacts with stakeholder organisations

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and relevant stakeholder organisations.

Article 109

Rules on transparency

To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles which is not of a confidential nature.

Article 110

Relations with relevant Community bodies

1. The Agency shall cooperate with other Community bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.

2. The Executive Director, having consulted the Committee on Risk Assessment and the European Food Safety Authority, shall establish rules of procedure concerning substances for which an opinion has been sought in a food safety context. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not otherwise affect the competences vested in the European Food Safety Authority.

3. This Title shall not affect the competences vested in the European Medicines Agency.

4. The Executive Director, having consulted the Committee on Risk Assessment, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work, shall establish rules of procedure concerning worker protection issues. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work and the European Agency for Health and Safety at Work.

Article 111

Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency. Member States, manufactures, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1).

For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.

TITLE XI

CLASSIFICATION AND LABELLING INVENTORY

Article 112

Scope

This Title shall apply to:

(a) substances subject to registration;

(b) substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC, where relevant, which results in the classification of the preparation as dangerous.

Article 113

Obligation to notify the Agency

1. Any manufacturer, producer of articles or importer, or group of manufacturers or producers of articles or importers, who place on the market a substance within the scope of Article 112, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 114, unless submitted as part of the registration:

(a) the identity(ies) of the manufacturer(s), producer(s) of articles or importer(s) responsible for placing the substance(s) on the market as specified in Section 1 of Annex VI;

(b) the identity of the substance(s) as specified in Sections 2.1 to 2.3.4 of Annex VI;

(c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;

(d) the hazard label for the substance(s), resulting from the application of Article 23(c) to (f), of Directive 67/548/EEC;

(e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

2. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.

3. The information listed in paragraph 1 shall be updated by the notifier(s) whenever:

(a) any new scientific or technical information is generated which results in a change to the classification and labelling of the substance;

(b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 2.

Article 114

Classification and labelling inventory

1. A classification and labelling inventory, listing the information referred to in Article 113(1), both for information notified under Article 113(1) as well as for information submitted as part of a registration, shall be established and maintained by the Agency in the form of a database. The information in this database identified in Article 119(1) shall be publicly accessible. The Agency shall grant access to the other data on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance with Article 29(1).

The Agency shall update the inventory when it receives updated information in accordance with Article 113(3).

2. In addition to the information referred to in paragraph 1, the Agency shall record the following information, where appropriate, against each entry:

(a) whether, in respect of the entry, there is a harmonised classification and labelling at Community level by inclusion in Annex I of Directive 67/548/EEC;

(b) whether, in respect of the entry, it is a joint entry between registrants of the same substance as per Article 11(1);

(c) if the entry differs from another entry on the inventory for the same substance;

(d) the relevant registration number(s), if available.

Article 115

Harmonisation of classification and labelling

1. Harmonised classification and labelling at Community level shall, from 1 June 2007, normally be added to Annex I of Directive 67/548/EEC for classification of a substance as carcinogenic, mutagenic or toxic for reproduction category 1, 2 or 3, or as a respiratory sensitiser. Harmonised classification and labelling for other effects may also be added to Annex I of Directive 67/548/EEC on a case-by-case basis if justification is provided demonstrating the need for action at Community level. To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XV.

2. The Committee for Risk Assessment shall adopt an opinion on the proposal, giving parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission, which shall take a decision in accordance with Article 4(3) of Directive 67/548/EEC.

Article 116

Transitional arrangements

The obligations set out in Article 113 shall apply from 1 December 2010.

TITLE XII

INFORMATION

Article 117

Reporting

1. Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127.

The first report shall be submitted by 1 June 2010.

2. Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately.

The first report shall be submitted by 1 June 2011.

3. Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.

The first report shall be submitted by 1 June 2011.

4. Every five years, the Commission shall publish a general report on:

(a) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and;

(b) the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods.

The first report shall be published by 1 June 2012.

Article 118

Access to information

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.

2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:

(a) details of the full composition of a preparation;

(b) without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;

(c) the precise tonnage of the substance or preparation manufactured or placed on the market;

(d) links between a manufacturer or importer and his distributors or downstream users.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.

3. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request, by 1 June 2008.

4. Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

Article 119

Electronic public access

1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):

(a) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g);

(b) if applicable, the name of the substance as given in EINECS;

(c) the classification and labelling of the substance;

(d) physicochemical data concerning the substance and on pathways and environmental fate;

(e) the result of each toxicological and ecotoxicological study;

(f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;

(g) the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;

(h) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

2. The following information on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;

(b) the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;

(c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);

(d) information, other than that listed in paragraph 1, contained in the safety data sheet;

(e) the trade name(s) of the substance;

(f) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;

(g) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:

(i) as an intermediate;

(ii) in scientific research and development;

(iii) in product and process orientated research and development.

Article 120

Cooperation with third countries and international organisations

Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals [1] or under Article 181a(3) of the Treaty, provided that both the following conditions are met:

(a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;

[1] OJ L 63, 6.3.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 777/2006 (OJ L 136, 24.5.2006, p. 9).

(b) the third party protects the confidential information as mutually agreed.

TITLE XIII

COMPETENT AUTHORITIES

Article 121

Appointment

Member States shall appoint the competent authority or competent authorities responsible for performing the tasks allotted to competent authorities under this Regulation and for cooperating with the Commission and the Agency in the implementation of this Regulation. Member States shall place adequate resources at the disposal of the competent authorities to enable them, in conjunction with any other available resources, to fulfil their tasks under this Regulation in a timely and effective manner.

Article 122

Cooperation between competent authorities

The competent authorities shall cooperate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States all the necessary and useful support to this end.

Article 123

Communication to the public of information on risks of substances

The competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in preparations or in articles, with a view to coordinating Member States in these activities.

Article 124

Other responsibilities

Competent authorities shall submit electronically to the Agency any available information that they hold on substances registered in accordance with Article 12(1) whose dossiers do not contain the full information referred to in Annex VII, in particular whether enforcement or monitoring activities have identified suspicions of risk. The competent authority shall update this information as appropriate.

Member States shall establish national helpdesks to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in particular in relation to the registration of substances in accordance with Article 12(1), in addition to the operational guidance documents provided by the Agency under Article 77(2)(g).

TITLE XIV

ENFORCEMENT

Article 125

Tasks of the Member States

Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.

Article 126

Penalties for non-compliance

Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them.

Article 127

Report

The report referred to in Article 117(1) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period. The common issues to be covered in the reports shall be agreed by the Forum. The Commission shall make these reports available to the Agency and the Forum.

TITLE XV

TRANSITIONAL AND FINAL PROVISIONS

Article 128

Free movement

1. Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a preparation or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.

2. Nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonise the requirements on manufacture, placing on the market or use.

Article 129

Safeguard clause

1. Where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a preparation or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.

2. The Commission shall take a decision in accordance with the procedure referred to in Article 133(3) within 60 days of receipt of the information from the Member State. This decision shall either:

(a) authorise the provisional measure for a time period defined in the decision; or

(b) require the Member State to revoke the provisional measure.

3. If, in the case of a decision as referred to in paragraph 2 (a), the provisional measure taken by the Member State consists in a restriction on the placing on the market or use of a substance, the Member State concerned shall initiate a Community restrictions procedure by submitting to the Agency a dossier, in accordance with Annex XV, within three months of the date of the Commission decision.

4. In the case of a decision as referred to in paragraph 2(a), the Commission shall consider whether this Regulation needs to be adapted.

Article 130

Statement of reasons for decisions

The competent authorities, the Agency and the Commission shall state the reasons for all decisions they take under this Regulation.

Article 131

Amendments to the Annexes

The Annexes may be amended in accordance with the procedure referred to in Article 133(4).

Article 132

Implementing legislation

The measures necessary to put the provisions of this Regulation efficiently into effect shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 133

Committee procedure

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. The Committee shall adopt its Rules of Procedure.

Article 134

Preparation of establishment of the Agency

1. The Commission shall afford the necessary support towards the establishment of the Agency.

2. For that purpose, until such time as the Executive Director takes up his duties following his appointment by the Management Board of the Agency in accordance with Article 84, the Commission, on behalf of the Agency, and using the budget provided for the latter, may:

(a) appoint personnel, including a person who shall fulfil the administrative functions of the Executive Director on an interim basis; and

(b) conclude other contracts.

Article 135

Transitional measures regarding notified substances

1. The requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 51 of this Regulation.

2. The requests to a notifier to provide further information for a substance in accordance with Article 16(1) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 52 of this Regulation.

Such substance shall be regarded as being included in the Community rolling action plan in accordance with Article 44(2) of this Regulation and shall be regarded as being chosen in accordance with Article 45(2) of this Regulation by the Member State whose competent authority has requested further information in accordance with Article 7(2) and Article 16(1) of Directive 67/548/EEC.

Article 136

Transitional measures regarding existing substances

1. The requests to manufacturers and importers to submit information to the Commission made by a Commission Regulation in application of Article 10(2) of Regulation (EEC) No 793/93, shall be considered as decisions adopted in accordance with Article 52 of this Regulation.

The competent authority for the substance shall be the competent authority from the Member State identified as rapporteur in accordance with Article 10(1) of Regulation (EEC) No 793/93 and shall carry out the tasks of Article 46(3) and Article 48 of this Regulation.

2. The requests to manufacturers and importers to submit information to the Commission made by a Commission Regulation in application of Article 12(2) of Regulation (EEC) No 793/93, shall be considered as decisions adopted in accordance with Article 52 of this Regulation. The Agency shall identify the competent authority for the substance to carry out the tasks of Article 46(3) and Article 48 of this Regulation.

3. A Member State whose rapporteur has not forwarded by 1 June 2008 the risk evaluation and, where appropriate, the strategy for limiting the risks, in accordance with Article 10(3) of Regulation (EEC) No 793/93, shall:

(a) document information on hazard and risk in accordance with Annex XV, Part B of this Regulation;

(b) apply Article 69(4) of this Regulation on the basis of the information referred to in point (a); and

(c) prepare a documentation of how it considers that any other risks identified would need to be addressed by action other than an amendment of Annex XVII of this Regulation.

The information referred to above shall be submitted to the Agency by 1 December 2008.

Article 137

Transitional measures regarding restrictions

1. By 1 June 2010, the Commission shall, if necessary, prepare a draft amendment to Annex XVII in accordance with either of the following:

(a) any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation (EEC) No 793/93 as far as it includes proposals for restrictions in accordance with Title VIII of this Regulation but for which a decision under Directive 76/769/EEC has not yet been taken;

(b) any proposal, which has been submitted to the relevant institutions but has not yet been adopted, concerning the introduction or the amendment of restrictions under Directive 76/769/EEC.

2. Until 1 June 2010, any dossier referred to in Article 129 (3) shall be submitted to the Commission. The Commission shall, if necessary, prepare a draft amendment to Annex XVII.

3. Any amendment to the restrictions adopted under Directive 76/769/EEC from 1 June 2007 shall be incorporated in Annex XVII with effect from 1 June 2009.

Article 138

Review

1. By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by 1 June 2014. When carrying out the review the Commission shall take into account all relevant factors, including:

(a) the costs for manufacturers and importers of drawing up the chemical safety reports;

(b) the distribution of costs between actors in the supply chain and the downstream user;

(c) the benefits for human health and the environment.

On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation.

2. The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:

(a) the risks posed by polymers in comparison with other substances;

(b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.

3. The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at one tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of one tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).

4. The Commission shall carry out a review of Annexes I, IV and V by 1 June 2008, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article 131.

5. The Commission shall carry out a review of Annex XIII by 1 December 2008, to assess the adequacy of the criteria for identifying substances which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, with a view to proposing an amendment to it, if appropriate, in accordance with the procedure referred to in Article 133(4).

6. By 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal.

7. By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60 (3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals.

8. By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the scope of Article 33 to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of that review, the Commission may, if appropriate, present legislative proposals to extend that obligation.

9. In accordance with the objective of promoting non-animal testing and the replacement, reduction or refinement of animal testing required under this Regulation, the Commission shall review the testing requirements of Section 8.7 of Annex VIII by 1 June 2019. On the basis of this review, while ensuring a high level of protection of health and the environment, the Commission may propose an amendment in accordance with the procedure referred to in Article 133(4).

Article 139

Repeals

Directive 91/155/EEC shall be repealed.

Directives 93/105/EC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) No 1488/94 shall be repealed with effect from 1 June 2008.

Directive 93/67/EEC shall be repealed with effect from 1 August 2008.

Directive 76/769/EEC shall be repealed with effect from 1 June 2009.

References to the repealed acts shall be construed as references to this Regulation.

Article 140

Amendment of Directive 1999/45/EC

Article 14 of Directive 1999/45/EC shall be deleted.

Article 141

Entry into force and application

1. This Regulation shall enter into force on 1 June 2007.

2. Titles II, III, V, VI, VII, XI and XII as well as Articles 128 and 136 shall apply from 1 June 2008.

3. Article 135 shall apply from 1 August 2008.

4. Title VIII and Annex XVII shall apply from 1 June 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 December 2006.

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	M. VANHANEN